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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,515	10/16/2003	Brian L. Newton	1600/162	5231
2101	7590	12/16/2004	EXAMINER	
BROMBERG & SUNSTEIN LLP			VIRDI, SUNDEEP	
125 SUMMER STREET			ART UNIT	
BOSTON, MA 02110-1618			PAPER NUMBER	

3763

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/687,515	NEWTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sundeep S Virdi	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20 February 2004</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6-8, 10, 13, 14, 16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Purdy et al (5,535,771).

Purdy discloses a medical valve (10) having an open mode to permit fluid flow and a closed mode to prevent fluid flow comprising a body (figure 4) forming an interior (figure 4), a proximal port (70) and a distal port (64) and a valving element (40) within the interior of the body controlling fluid flow between the proximal and distal ports, the valving element including a resilient member (42) and a plug (57), the resilient member forming a variable volume fluid chamber (31) within the interior of the body, the plug cooperating with the resilient member to provide an internal seal (57 in conjunction with 42 prevents any fluid from entering into the resilient structure and instead allows for it to be directed around into the fluid chamber and channels formed by the outer surface of the resilient member) within the interior of the body, the internal seal being spaced from the proximal port (70), the plug being capable of radially expanding the resilient member when the valve transitions from the closed mode to the open mode (while the drawings do not indicate radial expansion, it is inherent that a resilient material such as silicone rubber (column 6, lines 60-67) will radially expand upon compression), the fluid

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chamber having a larger volume when in the open mode than when in the closed mode (when resilient member 42 is pushed down by plug 57, a flow path is opened, such flow path increasing the volume of fluid chamber 31).

With regards to claim 6, Purdy et al discloses the interior including a stop (32), the plug being capable of longitudinally moving distally within the interior to contact the stop (47), the plug being capable of radially expanding the resilient member after the plug contacts the stop (once the plug 57 contacts the stop 47, it will push down on resilient member 42 in order to cause axial compression of 42, which as discussed above will inherently result in the radial compression of 42).

With regards to claim 7, the medical valve includes a distal end (57), the resilient member has a distal end (40), the plug distal end cooperating with the resilient member open distal end to form an internal seal (57 in conjunction with 42).

With regards to claim 8, Purdy et al discloses the internal seal being closed when the resilient member open distal end is occluded by the plug distal end (figure 4).

With regards to claims 13 and 18, Purdy et al discloses a plug member at least in part within a resilient member (bottom legs under 57 are within resilient member 42).

3. Claims 1, 7, 8, 10, 13, 14, 16, 18 and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Luther (4,842,591).

Luther discloses a medical valve (9) having an open mode to permit fluid flow and a closed mode to prevent fluid flow comprising a body (figure 2) forming an interior (figure 2), a proximal port (31) and a distal port (11) and a valving element (20) within the interior of the body controlling fluid flow between the proximal and distal ports, the

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valving element including a resilient member (34) and a plug (35), the resilient member forming a variable volume fluid chamber (interior as indicated by the arrows demonstrating fluid flow, it is variable volume because when the resilient member is opened the volume of the interior with fluid is increased) within the interior of the body, the plug cooperating with the resilient member to provide an internal seal (contact point between the legs of the plug 35 and the resilient member 34) within the interior of the body, the internal seal being spaced from the proximal port (31), the plug being capable of radially expanding the resilient member when the valve transitions from the closed mode to the open mode (when resilient member 34 is pushed apart and open, each face as indicated by 34 in figure 3 is expanded radially upon opening), the fluid chamber having a larger volume when in the open mode than when in the closed mode.

With regards to claims 13 and 18, Luther discloses a plug member at least in part within a resilient member (legs of plug member 35 are within the resilient member 34 when the plug pushes upon the resilient member (see figure 3).

***Claim Rejections - 35 USC § 103***

4. Claims 3-5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy et al in view of Paradis (6,068,011).

Purdy et al discloses the claimed invention as discussed above. However, Purdy et al does not disclose a plug including a plurality of legs that bow outwardly upon the application of a distally directed force and that normally bow outwardly, and include a leg separator to prevent contact of the legs.

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Paradis discloses a plug (20) including a plurality of legs (83-1 and 83-2) that bow outwardly upon the application of a distally directed force (abstract, lines 4-7) and that normally bow outwardly (figure 8A), and include a leg separator (legs inside of 83-1 and 83-2) for the purpose of providing a return force to the plug to push it back to its initial position (abstract, lines 4-7).

It would have been obvious to one of ordinary skill in the art to modify the device of Purdy et al by adding a plurality of legs that bow outwardly upon the application of a distally directed force and that normally bow outwardly and include a leg separator for the purpose of providing a return force to the plug to more effectively push it back to its initial position.

5. Claims 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy et al in view of Paradis (6,168,137).

Purdy et al discloses the claimed invention as discussed above. However, Purdy does not disclose the use of a valve element that is swabbable.

Paradis teaches the use of a swabbable valve element for the purpose of cleansing the valve element (column 2, lines 13-15).

It would have been obvious to one of ordinary skill in the art to modify the device of Purdy et al by using a swabbable valve element in order to cleanse the valve element.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luther.

Luther discloses the claimed invention as discussed above. However, Luther does not disclose a split plug member forming at least two portions with separable

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opposing faces, the opposing faces being substantially flush against each other when in the closed mode.

Luther does disclose a split in the resilient member 34 (see figures 2 and 3) forming at least two portions with separable opposing faces, the opposing faces being substantially flush against each other when in the closed mode.

It would have been obvious to one of ordinary skill in the art to modify the plug 35 and replace permeable membrane of 35 with a split similar to the split in the resilient member in order to permit more efficient fluid flow through the plug.

7. Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther in view of Daugherty et al (5,950,986).

Luther discloses the claimed invention as discussed above. However, Luther does not disclose the use of a proximal seal at the proximal port spaced from an internal seal.

Daugherty teaches the use of a proximal seal (column 4, lines 39-44) that prevents fluid from flowing into areas other than the desired fluid path.

It would have been obvious to one of ordinary skill in the art to modify the valve device of Luther and utilize a proximal seal near the proximal port, which would inherently be spaced from the internal seal since the internal seal is spaced from the proximal port, in order to prevent fluid from permeating regions of the valve into areas outside of the desired flow path prior to the fluid contacting the internal seal.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luther in view of Daugherty et al and further in view of Paradis.

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Luther and Daugherty disclose the claimed invention as discussed above. However, they do not teach the use of a valve element that is swabbable.

Paradis teaches the use of a swabbable valve element for the purpose of cleansing the valve element (column 2, lines 13-15).

It would have been obvious to one of ordinary skill in the art to modify the device of Luther and Daugherty et al by using a swabbable valve element in order to cleanse the valve element.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sivert (4,915,687) discloses a needleless injection port arrangement which demonstrates how a resilient member that is axially compressed will radially expand.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sundeeep S Viridi whose telephone number is 571-272-4969. The examiner can normally be reached on M-F 9am-5:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sundeep Viridi  
Art Unit 3763



MICHAEL J. HAYES  
PRIMARY EXAMINER